version：1.0
date：2023.10.29

Quantitative rating scale based on preoperative prediction of lymph node dissection in patients with thyroid cancer

Informed Consent Form

NCT ID：Not yet assigned

Date of document：2023.10.29

Informed Consent Form

Notice to Respondents
Dear Respondents:

You are invited to participate in a study of a quantitative rating scale based on preoperative prediction of whether to perform lymph node dissection in thyroid cancer patients, with Liu Yang as the principal investigator, which is undertaken by the Department of General Surgery, the Second Affiliated Hospital of Xi'an Jiaotong University, and the project is self-funded. This information sheet provides you with information to help you decide whether or not to participate in this study. This information note provides you with information to help you decide whether or not to participate in this research. Please read it carefully and if you have any questions, please ask the investigator in charge of the study.

Your participation in this study is voluntary. This study has been reviewed by the Ethics Review Committee of the Second Affiliated Hospital of Xi'an Jiaotong University.

Purpose of the study:

1.Background significance:The incidence of papillary thyroid carcinoma (PTC) has been on the rise in recent years, and lymph node metastasis is present in 20%-50% of PTC patients. Usually, lymph node involvement in PTC patients is related to the recurrence of PTC in patients after surgery, and 30% of patients recur without lymph node dissection, among which the risk of cervical central lymph node metastasis is the greatest, so it seems to be a good choice to perform lymph node dissection for patients after thyroidectomy, but in fact, there is a controversy at home and abroad as to whether to perform lymph node dissection or not. The 2021 Chinese Society of Clinical Oncology (CSCO) guidelines for the diagnosis and treatment of differentiated thyroid cancer state that prophylactic central lymph node dissection (PCND) may increase the incidence of postoperative complications, but due to the high metastatic rate of PTC and the ability of PCND to effectively prevent recurrence and reoperation, countries in the East Asian region perform prophylactic lymph node dissection on almost all patients with PTC. However, for more countries in Europe and the United States, performing PCND has become a non-essential, individualized option. The aim of this study is to collect multifactorial data from more than 1,000 patients who have undergone previous thyroidectomy from 2021 to 2023, and to develop a novel scoring scale that can be used to individualize patients' scores based on a variety of factors prior to surgery, so that patients can be more accurately predicted to have lymph node metastasis and need prophylactic lymph node dissection prior to surgery, and patients who do not need dissection can avoid surgery. For patients who do not need lymph node dissection,

complications caused by surgery can be avoided, while for patients who do have lymph node metastasis, recurrence of their cancer can be prevented. This will change the status quo of not being able to accurately determine the actual situation through simple preoperative examination or performing prophylactic lymph node dissection for all PTC patients.

2. Research process: 1. Patient characteristics: Inclusion criteria are as follows: 1. Patients with papillary thyroid cancer; 2. Minimum age of 16 years old, maximum age of 80 years old. Exclusion criteria: 1. age less than 16 years old; 2. postoperative pathology suggesting that there are other types of tumors, such as medullary carcinoma or undifferentiated carcinoma. 2.Data collection We collected multifactorial data from about 1000 patients who had undergone previous thyroidectomy from 2021 to 2023, including gender, height, age, weight, diameter of the tumor at the primary focus, tumor limitation at the primary focus, lymph node metastasis, and invasion, preoperative ultrasound manifestations, preoperative laboratory results, pathological results, and genetic testing results, etc., and screened the usable data from these data The data were retained for analysis. According to the retained data after screening, classical machine learning algorithms are used to select features and select factors with greater relevance to the results, and then, with the help of data visualization, the specific quantitative relationship between each factor and the results is determined according to the distribution of the available data, and the quantitative scoring table is created. 4. Clinical validation The completed quantitative scale will be validated in the clinic. New patients will be scored on the scale to assess the need for prophylactic lymph node dissection, and the accuracy of the quantitative scale will be assessed and validated during and after surgery. If you agree to take part in this study, we will talk to you or your family members about the study and ask you to provide information about your disease, including the course of the disease, your family history, previous visits to the doctor, and the results of any tests you may have had. Each participant will be numbered and a study file will be created).

3. Risks and discomforts: For you, there may be some psychological discomforts in communicating and talking with us.

4. Benefits: By studying your information data, it will help to obtain scientific research data, which will provide important evidence for disease diagnosis and treatment, biomedical scientific research, etc., and produce certain social value. Privacy: If you decide to participate in this study, your participation in the study and your personal information during the study will be kept confidential. The investigator in charge and other researchers will use your medical information to conduct the study. This information may include your name, address, telephone number, medical history, and information obtained at the time of your research visit. Your file will be kept in a locked file cabinet and will be accessible only to the researcher. To ensure that the research is conducted in accordance with the regulations, members of the government administration or the ethical review board

are required to have access to your personal data at the research unit when necessary. The results of this study will be published without disclosing any of your personal data.

You may choose not to participate in this study, or you may request to withdraw from the study at any time by notifying the researcher that your data will not be included in the results of the study, and none of your rights or interests will be affected as a result.

The investigator may terminate your continued participation in this study if you do not comply with the study plan, or if a study-related injury occurs or for any other reason.

You may be kept informed of information about this study and its progress, and you may contact the appropriate person if you have questions about this study, or if you experience any discomfort or injury during the study, or if you have questions about the rights of participants in this study.

Informed Consent Signature Page

Informed Consent Statement:

I have been informed about the purpose, background, procedures, risks and benefits of this study.

I was given plenty of time and opportunity to ask questions and the questions were answered to my satisfaction.

I have also been told who to contact when I have questions, want to talk about difficulties, concerns, suggestions for the study, or want to get further information or help with the study.

I have read this informed consent form.

My participation in this study is voluntary.

I have been informed that I may choose not to participate in this study or withdraw at any time without discrimination or retaliation by notifying the researcher, and that none of my rights will be affected as a result.

The investigator may terminate my continued participation in this study if I fail to comply with the study plan, or if a study-related injury occurs or for any other reason.

I will receive a signed copy of the Informed Consent Form with my signature and the investigator's signature.

Subject's name: _____ Contact number: _____

Subject's signature: _____

Date: _____ _Year _____ _Month _____

I have accurately communicated this document to the subject and he/she has accurately read this informed consent form and had the opportunity to ask

questions.

Investigator's name: _____ Contact phone number: _____

Signature of Investigator: _____

Date: _____ _Year _____ month _____ day

(Note: Witness signature is required if the subject is illiterate and fashion, and proxy signature is required if the subject is incapacitated)